

Appl. No. 09/917,278
Amdt. Dated June 29, 2004
Reply to Office action of March 2, 2004

REMARKS/ARGUMENTS

The Official Action dated March 2, 2004 has been carefully considered. It is believed that the following comments and amended claims represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

35 USC §112, Second Paragraph

The Examiner has objected to claim 14 under 35 USC §112, second paragraph as being indefinite. In response, claim 14 has been amended to depend from claim 12 as suggested by the Examiner.

In view of the foregoing, we respectfully request that the objection to claim 14 under 35 USC §112, second paragraph be withdrawn.

35 USC §112, First Paragraph

The Examiner has objected to claims 10-14 under 35 USC §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. We respectfully disagree with the Examiner for the reasons that follow.

The present inventors have determined that administering an antibody to CD200 can be used to treat cancers wherein the cancer is associated with elevated CD200 levels. The specification provides sufficient guidance to enable the skilled artisan to practice the method without undue experimentation. We disagree with the portion of the Examiner's statement that we have underlined: "Although methods exist for determining if a given tumor expresses CD200 or if tumor immunization enhances CD200 expression, the skilled artisan requires guidance as to which tumor types would be expected to meet these criteria." As the Examiner clearly sets out in the first part of the statement, methods exist to enable a skilled artisan to determine whether or not a

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particular tumor could be treated by administering antibodies to CD200. As a result, a skilled artisan does not need to know in advance which tumors are treatable by the present invention as he/she can readily determine if the presence of the tumor is associated with elevated CD200 levels. The level of experimentation required in order to determine which tumors are treatable is neither undue nor unreasonable. Further, the specification teaches in the working examples how one could determine whether or not CD200 levels are increased.

We note the Examiner's statement that "post filing data references showing that other cancers besides the working examples described supra express or induce CD200 do not correct for the lack of guidance provided in the specification as filed as to which cancers fall within this genus". The references were not provided in order to support the enablement of the disclosure as filed, but rather to demonstrate that the determination by the inventors that CD200 was involved in a tumor immunity has now been confirmed by several independent sources.

The Examiner has also questioned some of the data provided in the application. First, the Examiner comments that the results shown in Figure 24A demonstrate that antibodies to CD200 improve tumor survival although "the effect was only seen in pre-immunized mice: administration of the antibody in mice without pre-immunization did not improve survival". The pre-immunization relates to the administration of a tumor that has been transfected with CD86. The purpose of the pre-immunization is to increase the levels of CD200 in order to render the animal susceptible to treatment with anti-CD200 antibodies. The Examiner further notes that "the specification notes that no improvement of survival was seen when mice were pre-immunized with CD80 transfected cells, then challenged and given anti-OX-2 antibody". As expected, anti-CD200 therapy did not work in that example as CD80 does not result in the increase in CD200 levels. Therefore, all of the data presented in that Example support the claims as the data demonstrates that antibodies to CD200 can result in improved survival in animals with increased CD200 levels.

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The Examiner also questions the data provided on pages 91-92 and Figure 30 which "shows that administration of anti-OX-2 was not by itself sufficient to reduce the number of lung nodules compared to PBS alone". Again, these results are consistent with the present invention as administration of a CD200 antibody would not lead to treatment of the tumor where there is no elevation of CD200 in the animal.

The Commissioner is hereby authorized to charge any deficiency in fees (including any claim fees) or credit any overpayment to our Deposit Account No. 02-2095.

In view of the foregoing, we submit that the application is in order for allowance and an early indication to that effect would be greatly appreciated. Should the Examiner like to discuss the matter, he is kindly requested to contact Micheline Gravelle at 416-957-1682 at his convenience.

Respectfully submitted,

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